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|--|---|----|---|--------------------------|----------------------|
| Substitute for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |   |    |   | <b>Complete if Known</b> |                      |
|  |   |    |   | Application Number       | 10/617,038           |
|  |   |    |   | Filing Date              | July 11, 2003        |
|  |   |    |   | First Named Inventor     | Andersen et al       |
|  |   |    |   | Group Art Unit           | <del>1614</del> 1645 |
|  |   |    |   | Examiner Name            | SWARTZ               |
| Sheet  | 1 | of | 1 | Attorney Docket Number   | SSISAUSA             |

| OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS |                       |   |                          |
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| Examiner Initials*                             | Cite No. <sup>1</sup> | Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), column(s), number(s), publisher, city and/or country where published | T <sup>2</sup>           |
| RLG  | MM                    | SINIGAGLIA ET AL, "A Malaria T-Cell Epitope Recognized in Association with Most Mouse and Human MHC Class II Molecules", Nature, Vol. 336, 6201, pp. 778-780, (December 22-29, 1988)  |                          |
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|  |                       |   |                          |
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|   |   |    | Group Art Unit           | 1645                   |          |
|   |   |    | Examiner Name            | SWARTZ                 |          |
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## OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS

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|---|-----------------------|---|-----------------|----------|
| D<br>E<br>F<br>G<br>H<br>I<br>J<br>K<br>L | D                     | SAMBROOK ET AL, molecular cloning, A laboratory manual, Cold Spring Harbor Laboratories, NY, (1989) XP-002091112  |                 |          |
|   | E                     | Anon. Global Tuberculosis Control, WHO Report. (2001)   |                 |          |
|   | F                     | BRANDT ET AL, ESAT-6 Subunit Vaccination against Mycobacterium Tuberculosis, Infection and Immunity, Vol. 68, No. 2, pp. 791-795 (Feb. 2000)  |                 |          |
|   | G                     | BOON ET AL, Journal of Bacteriology, Vol. 183, No. 8 pp. 2672-2676, (April 2001)  |                 |          |
|   | H                     | DOHERTY ET AL, Immune Responses to the Mycobacterium Tuberculosis-Specific Antigen ESAT-6 Signal Subclinical Infection among Contacts of Tuberculosis Patients, Journal of Clinical Microbiology, Vol. 40, No. 2, pp. 704-706, (February 2002)  |                 |          |
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|   | K                     | MANGANELLI ET AL, The Mycobacterium Tuberculosis ECF Sigma Factor $\sigma^E$ : Role in Global Gene Expression and Survival in Macrophages, Molecular Microbiology, Vol. 41, No. 2, pp. 423-437, (May 2001)  |                 |          |
|   | L                     | MONAHAN ET AL, Differential Expression of Mycobacterial Proteins Following Phagocytosis by Macrophages, Microbiology, 147, pp. 459-471, (2001)  |                 |          |
| Examiner Signature                        | R P Swartz            |   | Date Considered | 10-19-05 |

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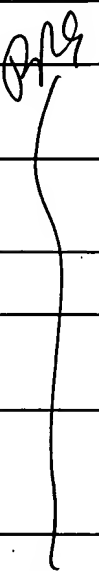
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|--|-----------------------|---|-----------------|----------|
|  | M                     | RAVN ET AL, Human T Cell Responses to the ESAT-6 Antigen from Mycobacterium Tuberculosis, The Journal of Infectious Diseases, 179, pp. 637-45, (1999)   |                 |          |
|  | N                     | ROSENKRANDS ET AL, Identification an Characterization of a 29-Kilodalton Protein from Mycobacterium Tuberculosis Culture Filtrate Recognized By Mouse Memory Effector Cells, Infection and Immunity, Vol. 66, No. 6, pp. 2728-2735, (June 1998)                     |                 |          |
|  | O                     | ROSENKRANDS ET AL, Hypoxic Response of Mycobacterium Tuberculosis Studied by Metabolic Labeling and Proteome Analysis of Cellular and Extracellular Proteins, Journal of Bacteriology, Vol. 184, No. 13, pp. 3485-3491, (July 2002)                                 |                 |          |
|  | P                     | SHERMAN ET AL, Regulation of the Mycobacterium Tuberculosis Hypoxic Response Gene Encoding $\alpha$ -Crystallin, PNAS, Vol. 98, No. 13, pp. 7534-7539, (June 19, 2001)  |                 |          |
|  | Q                     | SKJØT ET AL, Comparative Evaluation of Low-Molecular-Mass Proteins form Mycobacterium Tuberculosis Identifies Members of the ESAT-6 Family as Immunodominant T-Cell Antigens, Infection and Immunity, Vol. 68, No. 1, pp. 214-220, (January 2000)                   |                 |          |
|  | R                     | VORDERMEIER ET AL, Correlation of ESAAT-6- Specific Gamma Interferon Production with Pathology in Cattle Following Mycobacterium Bovis BCG Vaccination against Experimental Bovine Tuberculosis, Infection and Immunity, Vol. 70, No. 6, pp. 3026-3032, (June 2002) |                 |          |
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|  | T                     | MERRIFIELD, Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide, J. Am. Chem. Soc., 85:2149, (July 20, 1963)  |                 |          |
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|  | W                     | ULMER ET AL, Polynucleotide Vaccines, Curr. Opin. Invest. Drugs, 2(9):983-989 (1993)  |                 |          |
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| [Signature]                                    | X                     | COTE-SIERRA ET AL, A New Membrane-bound OprI lipoprotein Expression Vector High Production of Heterologous Fusion Proteins in Gram (-) Bacteria and the Implications for Oral Vaccination, Gene 221 pp. 25-34, (August 10, 1998)                                    |                 |          |
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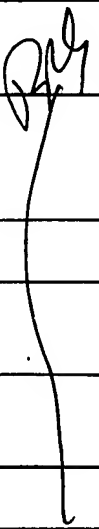
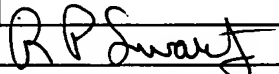


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|  | GG                    | NAGAI ET AL, Isolation and Partial Characterization of Major Protein Antigens in the Culture Fluid of Mycobacterium Tuberculosis, Infection and Immunity, Vol. 59, No. 1, pp. 372-382, (January 1991)  |                |
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